

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

### I. Status of the Claims

Claims 1-27, 37-38, 41, 44-50 and 61-63 were cancelled previously. Claims 28-31 and 60 have been amended, with exemplary support for the claim amendments found in the original specification, at page 16, lines 24-35. Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 28-36, 39, 40, 42, 43, 51-60 and 64-72 will be pending.

### II. Priority

The Examiner incorrectly recorded the effective filing date of the present application to be October 9, 1997. As shown in the table below, the present application is entitled to priority of U.S. Patent Application No. 08/394,103, filed on February 24, 1995. Specifically, the present application, filed on May 25, 2000, is a divisional of Application Serial No. 08/948,216, filed on October 9, 1997, and issued as U.S. Patent No. 6,264,922 on July 24, 2001, which is a continuation of Application Serial No. 08/589,681, filed on January 19, 1996 (abandoned as of March 4, 1998), which is a continuation-in-part of Application Serial No. 08/394,103, filed on February 24, 1995 (abandoned as of July 2, 1997). Thus: (1) the present application, filed on May 25, 2000, was filed before the parent '216 application issued as a patent on July 24, 2001; (2) the parent '216 application was filed on October 9, 1997, which was before the grandparent '681 application was abandoned on March 4, 1998; and (3) the grandparent '681 application was filed on January 19, 1996, which was before the great-grandparent '103 application was abandoned on July 2, 1997.

Application Number	Filing Date	Abandonment/Issue Date	Type of Application
09/577,489	05/25/2000	N/A	Divisional application of:
Parent 08/948,216, now U.S. Patent No. 6,264,922,	10/09/1997	issued on 7/24/2001	Continuation application of:
Grandparent 08/589,681	01/16/1996	Abandoned as of 03/04/1998	Continuation-in-part application of
Great-grandparent 08/394,103	02/24/1995	Abandoned as of 07/02/1997	

Because each application was filed during the pendency of the corresponding parent application, the present application benefits from the earliest priority date of February 24, 1995. Moreover, the new application transmittal filed on May 25, 2000 identifies the present application as a divisional application of the '216 application (the '922 patent). The cover page of the '922 patent shows the priority claims to the '681 application and to the '103 application, respectively. Accordingly, Applicants submit herewith an ADS with the correct priority information and respectfully request the Examiner record the correct effective filing date.

### **III. Statement of the Substance of the Interview**

Applicants thank Examiner James Alstrum-Acevedo for his confirmation that the present Office Action is non-final, during a teleconference with Ms. Stella Walker, who contacted Examiner Alstrum-Acevedo on behalf of Applicants' representative, Michele Simkin.

### **IV. Rejection of Claims under 35 U.S.C. §112, second paragraph**

Claim 32 is rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse the rejection.

The Examiner alleges that claim 32 is indefinite because the claim recites the broad phrase “polymer,” which overlaps with narrower recitations of specific polymers, such as polyvinyl alcohol, polyvinylpyrrolidone, etc. Contrary to the Examiner’s allegation, MPEP 2173.05(h) explicitly states that “[t]he use of Markush claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims.”

The Examiner’s construction of the claim language directly contravenes the definition of a Markush group, which presents a group of *alternative* expressions. Because each member recited by the Markush group of claim 32 is clear, the rejection lacks valid basis and therefore should be withdrawn.

**V. Rejection of Claims under 35 U.S.C. §103(a)**

Claims 28-36, 39-40, 42-43, 51-60 and 64-72 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over BECOTIDE® in view of U.S. Patent No. 5,008,114 to Lovrecich (“Lovrecich”) and U.S. Patent No. 5,525,623 to Spear et al. (“Spear”), as evidenced by U.S. Patent No. 5,049,389 to Radhakrishnan (“Radhakrishnan”). Applicants respectfully traverse the rejection.

As the Examiner has acknowledged, BECOTIDE® fails to teach several essential elements recited in claim 28, such as an effective average particle size of less than 1000 nm, the crystalline nature of the beclomethasone particles, and a surface modifier adsorbed on the surface of the beclomethasone particles.

To bridge the gap of the primary reference, the Examiner relies on Figure 4 of Radhakrishnan for the alleged teaching of the particle size. In the present application, “an effective average particle size of less than about 1000 nm” is defined as at least 90% of the particles having a weight average particle size of less than 1000 nm. *See* specification, page 16, lines 24-27. A close examination of Radhakrishnan’s Figure 4 reveals that at least 90% of BECOTUDE® has a particle size of about 8 microns, which is significantly larger than the

claimed effective average particle size of less than 1000 nm. Therefore, contrary to the Examiner's contention, BECOTUDE® does not read on the claimed particle size.

The Examiner further cites Lovrecich for the alleged teaching of smaller particle size. Nevertheless, the rationale supporting the rejection is defective because: (i) the motivation to combine the references is lacking; and (ii) one skilled in the art would not have arrived at the claimed invention based on the combined teachings of the cited references.

Concerning point (i), Lovrecich has a very general disclosure that the active substance can be anti-hypertensives, anti-inflammatories, anti-anxiety agents, antidepressives, corticosteroids and antibactericides. In a preferred embodiment, Lovrecich discloses diazepam, digoxin, griseofulvin, methylhydroxy-progesterone acetate, nifedipine, megestrol acetate, haloperidol, nicardipine, diltiazem and etoposide to be the preferred active substances. *See* Lovrecich, column 2, lines 6-14. Because Lovrecich fails to teach beclomethasone, one skilled in the art would not have been motivated to combine the cited references in an attempt to obtain the claimed invention.

Turning to point (ii), Lovrecich's composition is completely different from an aerosol composition comprising aqueous droplets of the claimed invention. Lovrecich's composition comprises a microporous support and an active substance incorporated in the microporous support and aims at improved solubility. *See* abstract and column 2, lines 54-68. As such, it is clear to one skilled in the art that Lovrecich's composition is in a solid form with active substance embedded in a microporous platform, which is distinguishable from the aerosol composition comprising aqueous droplets of the claimed invention.

Moreover, Lovrecich describes that the substances used as microporous support are silicas, silicates, zeolites, aluminas, activated carbons and microporous polymer substances (column 2, lines 22-25). The skilled artisan would have appreciated that Lovrecich's microporous support are highly toxic for deep lung delivery. For example, inhalation of

asbestos, a naturally occurring form of silicates, causes serious illness, such as mesothelioma, lung cancer and asbestosis. Accordingly, one would not have combined the teachings of the primary reference and Lovrecich to obtain the aerosol composition of the claimed invention.

The Examiner cites Spear for the alleged teaching of jet nebulizers and ultrasonic nebulizers, but Spear fails to cure the deficiencies of BECOTUDE® and Lovrecich as discussed *supra*. Accordingly, Applicants respectfully request withdrawal of the rejection.

#### CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

By Michele M. Simkin

Date: January 14, 2009

FOLEY & LARDNER LLP  
Customer Number: 31049  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

Michele M. Simkin  
Registration No. 34,717  
By Yang Tang  
Registration No. 55,663